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| 09/714,093      | 11/16/2000  | Frank Butaric        | CRD-834             | 5116             |

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| EXAMINER |
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MILLER, CHERYL L

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| ART UNIT | PAPER NUMBER |
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3738

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/714,093 | <b>Applicant(s)</b><br>BUTARIC ET AL. |  |
|                              | <b>Examiner</b><br>Cheryl Miller     | <b>Art Unit</b><br>3738               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.  
 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-5 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1 and 3-5 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Attachment</u>                         |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments with respect to claims 1 and 3-5 have been considered but are moot in view of the new ground(s) of rejection.

The Fogarty rejection previously applied, has been overcome by the present amendment. In regards to applicant's arguments to the previously applied 103 rejections, that the references taken in combination fail to disclose all limitations of the claim, this is found non-persuasive by the examiner for the reasons below. It is also noted to the applicant, that the argument of the references not disclosing a proximal end hoop uncovered by graft material, is not persuasive because this limitation is not claimed, in fact not even a graft is claimed, only a stent *capable* of being attached to a graft.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim (USPN 6,270,524 B1, cited in previous office action) in view of Lombardi et al. (USPN 6,579,314 B1, cited in previous office action) and further in view of Freidberg et al. (USPN 6,699,277 B1, cited in previous office action). Referring to claims 1 and 5, Kim discloses a monolithic (rigid or welded connections) radially expandable stent (see figure 2A) having proximal and distal open ends and a longitudinal axis therebetween comprising a plurality of

hoops (end hoops in fig.2A) comprising a plurality of interconnected struts (20) forming a substantially diamond shape configuration (end hoops in fig.2A are diamond shaped), the stent having a proximal end hoop and a distal end hoop, wherein the distal end hoop and the proximal end hoop are configured to have greater radial and longitudinal strength than the hoops therebetween (will inherently be stronger in both directions due to their shape being more interconnected than the rings 14 therebetween), a plurality of sinusoidal rings (14) connecting adjacent hoops (end diamond hoops) to one another, the sinusoidal rings being formed from a plurality of alternating struts (20), the plurality of alternating struts (20) being substantially shorter in length than the plurality of interconnected struts (20) of the plurality of hoops (see attachment 1), wherein the union (connector 22 considered the union) of each of the plurality of sinusoidal rings and each of the plurality of hoops is made at the apex of at least one diamond configuration of the plurality of hoops and the apex of at least one intersection of the plurality of alternating struts of the sinusoidal rings (22 unions an apex of two 21's with other apex of two 21's; 22 being the union) and proximal and distal attachment devices (Kim discloses the stent may be attached to a graft by any suitable manner and discloses several examples, col. 11, lines 29-39, 52-54), the proximal attachment device (any suitable method disclosed, such as bonding) being positioned distal of the proximal open end of the stent (is positioned at various locations along the stent, so therefore also distal of the proximal end) such that the proximal end hoop of the stent is configured to be exposed to a body vessel (will be inherently exposed, if the graft is not present, because applicant has not positively claimed a graft), wherein the stent is a monolithic structure. Kim discloses the invention substantially as claimed, however does not disclose *flared end hoops* nor the *particular attachment device* claimed. Lombardi teaches in the

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same field of radially expandable stents, a stent (12) having a plurality of hoops and plurality of sinusoidal connecting rings, *and additionally flaring the stent ends* (14; fig.1) for the purpose of *better anchorage of the stent in the vessel* (col.4, lines 54-57; col.6, line 46-49). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Kim's radially expandable stent with Lombardi's teaching of flaring ends of stents, in order to provide a stent which will better anchor in the vessel. Also, although Kim (in view of Lombardi) discloses attaching a stent to a graft by any suitable method and lists several examples (col.11, lines 28-38, 52-54), Kim does not disclose the *particular* method claimed (tabs with openings, monolithic with the stent struts). Freidberg teaches in the same field of attachment devices for radially expandable stents, an *alternative method for attaching a stent to a graft*, comprising proximal and distal attachment devices (51, see figures 11-14) placed on any conventional stent (col.3, lines 7-14) comprising tabs (52, 57, 59) formed from the joining of two struts (struts on both sides of tab 52, 57, and 59) and having at least two apertures (eyelets, 53, 58, 60) spaced from the end of the stent, *in order to attach a stent (55) to a graft (22), so that restenosis is reduced in the vessel* (col.2, lines 1-5, 59-67; col.8, lines 35-57). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Kim in view of Lombardi's stent structure with the disclosure of possible attachment devices, with Freidberg's teaching of an alternative attachment devices on a stent, in order to provide an additional method of attaching a graft to a stent, thereby reducing any chance of restenosis in the vessel.

Referring to claims 3-4, Kim discloses a self-expanding stent, made of superelastic nickel titanium (col.7, lines 64-67; col.8, lines 34-50).

Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berry et al. (USPN 6,231,598 B1, cited in previous office action) in view of Freidberg et al. (USPN 6,699,277 B1, cited in previous office action). Berry discloses a radially expandable stent (see figures 15, 16, 17, 18, and 20; col.8, lines 36-39) having proximal and distal open ends and a longitudinal axis between, the stent deployable in a body vessel, the stent comprising a plurality of hoops (14) comprising a plurality of interconnected struts (15, 16, 13) forming a substantially diamond shaped pattern (figs.15, 16, 17, 18, 20), the stent having a proximal (63) and a distal hoop (63'), the end hoops configured to have greater radial and longitudinal strength than the hoops between (col.17, lines 22-25), and the proximal hoop being flared (col.21 line 62-col.22 line 8), a plurality of sinusoidal rings (75, 108, 21) connecting adjacent hoops (col.9, lines 1-3; col.10, lines 26-32), the rings (75, 108, 21) being formed from a plurality of alternating struts, the plurality of alternating struts being substantially shorter in length than the plurality of interconnected struts of the plurality of hoops (14), see figures 15-20, wherein the union of each of the plurality of sinusoidal rings and each of the plurality of hoops is made at the apex of at least one diamond configuration of the plurality of hoops and the apex of at least one intersection of the plurality of alternating struts of the sinusoidal rings (unions 36, 68; see figures 15, 17, 18), wherein the parts of the stent form a unitary structure (see figures) formed from a single element (may have originated from one sheet or tube in the manufacturing process, or since it is a single material stent, the parts are formed of a single metal, see arguments above). Berry does not disclose however, *proximal and distal attachment devices* as part of the stent. Freidberg teaches in the same field of radially expandable stents, *proximal and distal attachment devices* (51, see

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*figures 11-14) placed on any conventional stent (col.3, lines 7-14) comprising tabs (52, 57, 59) formed from the joining of two struts (struts on both sides of tab 52, 57, and 59) and having at least two apertures (eyelets, 53, 58, 60) spaced from the end of the stent, in order to attach a stent (55) to a graft (22), so that restenosis is reduced in the vessel (col.2, lines 1-5, 59-67; col.8, lines 35-57).* It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the stent structure of Berry with Freidberg's teaching of attachment devices and their location, on a stent, in order to attach a graft to a stent, thereby reducing any chance of restenosis in the vessel.

Referring to claims 3-4, Berry discloses a self-expanding stent, made of superelastic nickel titanium (col.8, lines 60-63; col.18, lines 45-62).

Referring to claim 5, Berry discloses an end hoop having a larger diameter than an adjacent hoop (col.22, lines 1-7).

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



**BRUCE SNOW  
PRIMARY EXAMINER**



